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Charles E. Van Horn
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
901 New York Ave, NW
Washington DC 20001-4413

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,795,864

NOTICE OF FINAL DETERMINATION
AND
REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 5,795,864, which claims the human drug product PRIALT® (ziconotide), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,280 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent and response to the requirement for an election of the patent for which the certificate of extension will issue may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent No. 5,364,842 based on the regulatory review period for the human drug product PRIALT® (ziconotide).

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. In the absence of an election by applicant within the one month time frame set forth above, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified patent will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted. (A certificate of extension will be issued to U.S. Patent No. 5,364,842 for a period of 5 years from the original expiry of U.S. Patent No. 5,364,842, unless applicant expressly elects U.S. Patent No. 5,795,864 for extension). In accordance with an express election of U.S. Patent No. 5,795,864 for term extension, the Director will issue to applicant, a certificate of extension of the term of U.S. Patent No. 5,795,864, under seal, for a period of 1,280 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 15, 2006, (71 Fed. Reg. 13409), would be 2,076 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2}(\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2}(1,973 - 1,476) + 1,828 \\ &= 2,076 \text{ days (5.7 years)}\end{aligned}$$

Since the regulatory review period began August 4, 1994, before the patent issued (August 18, 1998), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From August 4, 1994, to and including August 18, 1998, is 1,476 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 2,076 days, would extend the patent from June 27, 2015 to March 3, 2021, which is beyond the 14-year limit (the approval date is December 28, 2004, thus the 14 year limit is December 28, 2018). The period of extension is thus limited to 1,280 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, June 27, 2015, to and including December 28, 2018, or 1,280 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,795,864
Granted:	August 18, 1998
Original Expiration Date ¹ :	June 27, 2015
Applicant:	Gary Arthur Amstutz, et al.
Owner of Record:	Elan Pharmaceuticals, Inc.
Title:	Stable Omega Conopeptide Formulations
Product Trade Name:	PRIALT® (ziconotide)
Term Extended:	1,280 days
Expiration Date of Extension:	December 28, 2018

¹Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

RE: PRIALT® (ziconotide)
FDA Docket No.: 2005E-0246

Attention: Beverly Friedman